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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/252,842	02/19/1999	CHARI STYLLI	AUROBIO.014A	4954

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EXAMINER

BEX, PATRICIA K

ART UNIT PAPER NUMBER

1743

DATE MAILED: 12/07/2001

12

Please find below and/or attached an Office communication concerning this application or proceeding.

ME/2

Office Action Summary

Application No.

09/252,842

Applicant(s)

STYLLI ET AL.

Examiner

P. Kathryn Bex

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 January 0103.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,8,10-12 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,8,10-12 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23, line 2, the new limitation "comprising at least approximately 25,000 addressable wells", is not supported within the instant specification, see Clean Version of Claims in Amendment filed October 05, 2001. Applicant points to page 49, lines 10-14 for support, however the cited section recites that the storage and retrieval module can store at least 200,000 discrete chemical on at least 2,000 work units and at least about 10,000,000 work units. No mention of 25,000 *addressable wells*.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23, line 2, the limitation "comprising at least approximately 2000 storage locations

for multi-well plates" in the Marked-up version of the claims and "comprising at least approximately 25,000 addressable wells" in the Clean version of the claims, creates confusion and uncertainty as to which *version* applicant is requesting examination. For examination purposes, Examiner has interpreted that Applicant intended a chemical storage apparatus comprising at least approximately 2,000 locations for multi-well plates, as recited in the Marked up version of the claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 20, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacIndoe, Jr. (USP 5,332,549) in view of Ishizaki *et al* (JP-6-207943).

MacIndoe, Jr teach an automatic analyzing apparatus comprising a chemical library 17 with storage locations 121 for plates, retrieving the selected set of chemical compounds in a multi-well plate, corresponding to the selected set of addressable chemical wells from an

addressable chemical storage module 17 (Fig. 1) with a programmable computer (CPU) which controls the automated robotic retriever 23 (column 9, lines 39-51), an automated transport pathway 37 coupled to the chemical library (column 4, lines 63-67) and a plurality of asynchronously operable automated liquid handling devices (pipettors) 25 1-2 coupled to the transport path. Note: MacIndoe, Jr. clearly teaches a programmable instrument system which controls the robotic retriever and other various assemblies, (column 2, line 19-25, column 2, line 59- column 3, line 12, column 5, lines 26-42, column 9, lines 39-51). MacIndoe Jr. also discloses the use of a buffer platform proximate 24 to the storage module (column 3, lines 4-12).

MacIndoe, Jr. fails to teach the returning the selected set of chemical compounds to the addressable chemical storage module via the bidirectional and parallel transport pathway.

Ishizaki *et al* do teach an automatic analyzer for retrieving a selected set of chemical compounds 2 from an addressable chemical storage module 3 (Fig. 1) with an automated robotic retriever 76 (Fig. 2), delivering the set of chemical compounds to an automated, bidirectional, parallel transport pathway 6 and delivering the set of chemical compounds to automated liquid handlers 10, 11 (Fig. 1) and returning the selected set of chemical compounds via the automated, bidirectional and parallel transport pathway 71 (abstract) and plate stacking storage buffer 73. Such use of a return line allows the analyzer to quickly and effectively carry out automated re-examination, thereby insuring accurate analysis (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the analyzer apparatus of MacIndoe, Jr. the conveyer capable of returning the selected set of chemical compounds via an automated transport pathway,

as taught by Ishizaki *et al*, in order to allow the analyzer to quickly and effectively carry out automated re-examination, thereby insuring accurate analysis (abstract).

In regard to the specific location of the buffer, it would have been obvious to one having ordinary skill in the art at the time the invention was made to situate the buffer at the ingress location of the storage, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

MacIndoe, Jr. does not explicitly teach the storage capacity of 1000 or 3000 multi-well plates. However, it would have been an obvious matter of design choice to one of ordinary skill in the art to include a storage module capable of storing 1000 to 3000 multi-well plates in order to increase the quantity of samples that a single laboratory can effectively handle without a loss in quality or increased error rates occurring due to increased throughput. Further, such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

8. Claims 8, 10-12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacIndoe, Jr. (USP 5,332,549) and Ishizaki *et al* (JP-6-207943), as applied to claim 20 above, in view of AllegroTM "Ultra High Throughput Screening System" by Zymark.

MacIndoe, Jr. and Ishizaki *et al* as discussed previously, fail to teach automated liquid handling devices capable of achieving a throughput of at least 100,000 chemical samples in a 24 hour period. Zymark does teach a computerized screening system with associated storage and retrieval modules for use with micro-titer plate formats. This system can handle 1,000 microtiter plates which read on addressable chemical wells in addressable chemical plates. Moreover, the

system can utilize 384 well micro-titer plates which means it can handle 384,000 samples per day, which is clearly over the at least 50,000 or 100,000 chemical samples per day.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the assay apparatus of MacIndoe, Jr. and Ishizaki the liquid handlers, as taught by Zymark, in order to increase throughput without completely redesigning their well defined 96-well plate assays.

9. Claims 1-3, 20, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashihara *et al* (USP 5,158,895) in view of Shuttleworth, Inc., "Flat Panel Display News" February 1996.

Ashihara *et al* teach an apparatus comprising a computer controlled robotic retriever 33 (column 15, line 37- column 16, line 22) for retrieval of a selected set of chemical compounds corresponding to the selected set of addressable chemical wells from an addressable chemical storage module 31 (Fig. 1) wherein each well contains a different chemical (column 3, lines 34-40), an automated transport pathway 71 which delivers the set of chemical compounds to automated liquid handlers (pipettors) 16 a-c (Fig. 2). Note: Ashihara *et al* teaches a programmable instrument system which controls the robotic retriever and other various assemblies (column 3, lines 60-63, column 7, lines 4-18).

Ashihara *et al* fail to teach an bi-directional and parallel transport path which is coupled to at least one plate stacking storage plate buffer. Shuttleworth, Inc. "Flat Panel Display News" does disclose the use of a transport pathway which is operably linked with local plate buffers which accumulates cassettes before feeding them to a vertical conveyer of a storage unit, see page 5, paragraph 2 and Figure on same page. Note: Since the conveyer system of Shuttleworth,

Inc. is clearly bi-directional, it inherently comprises the capability to return plates to the storage facility.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the automatic analyzer of Ashihara *et al* the cassette transportation with local buffers, as taught by Shuttleworth, Inc. "Flat Panel Display News", in order to greatly simplify the automation required and dramatically improve the total system reliability, see page 5, paragraph 1, last line.

Regarding the use of a plate comprising 96 chemical wells and the storage capacity of 1000 or 3000 multi-well plates, Ashihara *et al* do not explicitly teach the a 96 well plate or a storage module with a storage capacity of 1000 or 3000 multi-well plates. However, it would have been an obvious matter of design choice to one of ordinary skill in the art to include a the use of a 96 multiwell plate and a storage module capable of storing 1000 or 3000 multi-well plates in order to increase the quantity of samples that a single laboratory can effectively handle without a loss in quality or increased error rates occurring due to increased throughput. Further, such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

10. Claims 8, 10-12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable Ashihara *et al* (USP 5,158,895) in view of Shuttleworth, Inc., "Flat Panel Display News" February 1996, as applied to claim 20 above, and further in view of AllegroTM "Ultra High Throughput Screening System" by Zymark.

Ashihara *et al* and Shuttleworth, Inc. as discussed previously, fail to teach automated

liquid handling devices capable of achieving a throughput of at least 100,000 chemical samples in a 24 hour period. Zymark does teach a computerized screening system with associated storage and retrieval modules for use with micro-titer plate formats. This system can handle 1,000 microtiter plates which read on addressable chemical wells in addressable chemical plates. Moreover, the system can utilize 384 well micro-titer plates which means it can handle 384,000 samples per day, which is clearly over the at least 100,000 chemical samples per day.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the analytical apparatus of Ashihara *et al* and Shuttleworth, Inc. the liquid handlers, as taught by Zymark, in order to increase throughput without completely redesigning their well defined 96-well plate assays.

Response to Arguments

11. Applicant's arguments filed February 7, 2001 have been fully considered but they are not persuasive.

In response to Applicant's argument that MacIndoe (USP 5,332,549) and Ashihara *et al* (USP 5,158,895) describe devices in which the wells containing test sample which are *manually* placed in the device is not germane to the issue since Applicant has not excluded such a limitation from the claims. The claims describe the automated *retrieval* of the multi-well plates containing a liquid sample, there is not disclosure of an automated loading device. Additionally, Applicant argues that the wells of MacIndoe and Ashihara *et al* are processed in a serial fashion. Examiner points out that no *parallel* processing of the wells is disclosed within the instant

claims. Moreover, the instant claims are drawn to the *structure* of an apparatus. Process limitations are not accorded patentable weight in an apparatus which is drawn to an apparatus.

Conclusion

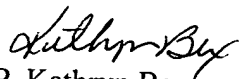
12. No claims allowed.

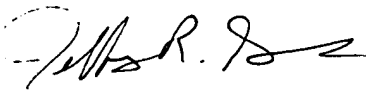
13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.


P. Kathryn Bex
Patent Examiner
AU 1743
12/3/01


JEFFREY SNAY
PRIMARY EXAMINER